

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Present Application:**

Applicant : David N. Krag  
Filed : March 22, 2001  
For : SYSTEM AND METHOD FOR BRACKETING AND REMOVING  
TISSUE

**Prior Application:**

Examiner : William Lewis  
Art Unit : 3731  
Application No. : March 22, 2001

Box Patent Application  
Commissioner for Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Dear Commissioner:

This communication is a preliminary amendment filed concurrently with a new divisional application claiming priority to Application No. 09/078,982, which was filed 14 May 1998 (the "Parent Application"). In keeping with 37 C.F.R. §1.121(c), following is a clean version of the entire set of pending claims upon entry of the present amendment, with claims added or cancelled by the present amendment being so noted. Since none of the remaining original claims are being amended, no separate appendix showing claim amendments is necessary under 37 C.F.R. §1.121(c). Please amend the application as follows:

**In the Specification:**

Amend the specification by inserting a new section before the "Technical Field" as follows:

**-- CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a divisional of pending United States Patent Application No. 09/078,982, filed May 14, 1998. --

In the Claims:

Please cancel claims 1-31, without prejudice.

1 32. A tissue anchor comprising:

- 2 a. an elongate tube having a central bore, a distal end and a proximal end,  
3 wherein said tube has at least one aperture adjacent said distal end;
- 4 b. an elongate member having a portion sized for receipt and axial movement in  
5 said central bore between a first position and a second position, wherein said  
6 elongate member includes a longitudinal axis and at least one anchor  
7 member attached to said portion; and
- 8 c. wherein said at least one anchor member is configured and positioned so  
9 that when said portion is in said first position said at least one anchor  
10 member is at least partially received in said elongate tube and when said  
11 portion is in said second position said at least one anchor member projects  
12 through said at least one aperture and extends transversely relative to said  
13 longitudinal axis.

1 33. A tissue anchor according to claim 32, further wherein said elongate tube has an  
2 outside diameter ranging from 0.5mm to 12mm.

1 34. A tissue anchor according to claim 32, wherein said outside diameter ranges from  
2 1mm to 3mm.

1 35. A tissue anchor according to claim 32, wherein said at least one anchor member  
2 includes four anchor members.

1 36. A tissue anchor according to claim 32, wherein said at least one anchor member  
2 has a curved configuration when said portion is in said second position.

Please cancel claims 37-64, without prejudice.

Please add the following as new claims 65-97:

- 1 65. (New) A tissue anchor according to claim 35, wherein said at least one aperture  
2 includes four apertures, with one aperture being associated with each anchor  
3 member.
- 1 66. (New) A tissue anchor according to claim 65, wherein each anchor member projects  
2 from its associated aperture when the elongate member is in its first position.
- 1 67. (New) A tissue anchor according to claim 32, wherein said at least one anchor  
2 member includes a barb adjacent an end thereof.
- 1 68. (New) A tissue anchor according to claim 32, wherein the distal end of the elongate  
2 tube is adapted to be advanced into a volume of tissue to position the at least one  
3 anchor member for stabilizing deployment into the tissue.
- 1 69. (New) A tissue anchor according to claim 68, wherein the distal end of the elongate  
2 tube is closed, said at least one aperture being spaced proximally from the distal  
3 end.
- 1 70. (New) A tissue anchor according to claim 69, wherein said at least one anchor  
2 member extends distally beyond a distal end of the elongate member when the  
3 elongate member is in its first position.
- 1 71. (New) A tissue anchor according to claim 70, wherein said at least one anchor  
2 member is curved when in an unbiased state.
- 1 72. (New) A tissue anchor according to claim 71, wherein said at least one anchor  
2 member is in its unbiased state when the elongate member is in its second position.
- 1 73. (New) A tissue anchor according to claim 71, wherein said at least one anchor  
2 member curves proximally when the elongate member is in its second position.

1 74. (New) A tissue anchor according to claim 32, wherein said portion of the elongate  
2 member is sized for a close sliding fit within the central bore of the elongate tube.

1 75. (New) A tissue anchor for stabilizing a tissue mass for surgical excision, comprising:

- 2 a. an elongate tube having a distal end adapted to be advanced into the tissue  
3 mass, a central bore, a wall, and a plurality of apertures extending through  
4 the wall;
- 5 b. a manually controllable actuator carried by the elongate tube and being  
6 moveable with respect to the elongate tube between a first position and a  
7 second position; and
- 8 c. a plurality of manually deployable anchor members, with one anchor member  
9 being associated with each aperture of the elongate tube, each of the anchor  
10 members being operatively connected to the actuator such that each anchor  
11 member assumes a retracted position when the actuator is in its first position  
12 and each anchor assumes an extended position when the actuator is in its  
13 second position, each anchor member in its retracted position having a major  
14 portion received within the central bore of the elongate tube, each anchor  
15 member in its extended position projecting outwardly from its associated  
16 aperture and assuming a curved configuration to facilitate stabilization of the  
17 tissue mass.

1 76. (New) A tissue anchor according to claim 75, wherein the apertures of the elongate  
2 tube are spaced proximally of the distal end.

1 77. (New) A tissue anchor according to claim 75, wherein the actuator comprises an  
2 elongate member sized for a close sliding fit within the central bore of the elongate  
3 tube.

1 78. (New) A tissue anchor according to claim 77, wherein the actuator further comprises  
2 a ring carried adjacent a proximal end of the elongate member.

1 79. (New) A tissue anchor according to claim 75, wherein the actuator further comprises  
2 a stop, the stop cooperating with the elongate tube to limit movement of the  
3 elongate member with respect to the elongate tube, thereby defining the second  
4 position of the actuator.

1 80. (New) A tissue anchor according to claim 75, wherein the actuator comprises an  
2 elongate member slidably received within the central bore of the elongate tube,  
3 each of the anchor means being attached to the elongate member for movement  
4 therewith.

1 81. (New) A tissue anchor according to claim 80, wherein the elongate member is  
2 moved distally as the actuator moves from its first position to its second position.

1 82. (New) A tissue anchor according to claim 75, wherein each anchor member projects  
2 from its associated aperture when the actuator is in its first position.

1 83. (New) A tissue anchor for stabilizing a tissue mass for surgical excision, comprising:  
2 a. an elongate tube having a closed distal end, a central bore, a wall, and four  
3 apertures extending through the wall;  
4 b. a rod having a manually engageable ring adjacent its proximal end and a  
5 length which is slidably received in the central bore of the elongate tube, the  
6 rod being moveable distally with respect to the elongate tube from a first  
7 position to a second position; and  
8 c. four anchor members, with one anchor member being associated with each  
9 aperture of the elongate tube, each of the anchor members being connected  
10 to the rod for movement therewith such that each anchor member assumes a  
11 retracted position when the rod is in its first position and each anchor  
12 member assumes an extended position when the rod is in its second  
13 position, each anchor member in its retracted position having a majority of its  
14 length received within the central bore of the elongate tube, each anchor  
15 member in its extended position projecting outwardly from its associated

16 aperture and assuming a curved configuration to facilitate stabilization of the  
17 tissue mass.

1 84. (New) A tissue anchor according to claim 83, wherein the apertures of the elongate  
2 tube are spaced proximally of the distal end.

1 85. (New) A tissue anchor according to claim 83, wherein the rod further comprises a  
2 stop, the stop cooperating with the elongate tube to limit movement of the rod with  
3 respect to the elongate tube, thereby defining the second position of the rod.

1 86. (New) A tissue anchor according to claim 83, wherein the anchor members are  
2 attached to the rod and extend distally beyond a distal end of the rod.

1 87. (New) A tissue anchor according to claim 83, wherein a small portion of each  
2 anchor member projects from its associated aperture when the rod is in its first  
3 position.

1 88. (New) A method of stabilizing a tissue mass using the tissue anchor of claim 83,  
2 comprising:

- 3 a. with the rod in its first position, advancing the distal end of the elongate tube  
4 into the tissue mass;  
5 b. thereafter, advancing the rod distally to its second position, thereby forcing  
6 the anchor members outwardly from the elongate tube and into the tissue  
7 mass to stabilize the tissue mass.

1 89. (New) A method according to claim 88, further comprising drawing the tissue anchor  
2 proximally after the anchor members are deployed in the tissue mass to apply  
3 tension to the tissue mass.

1 90. (New) A method according to claim 88, further comprising leaning the elongate tube  
2 and the elongate rod after the anchor members are deployed in the tissue mass to  
3 facilitate surgical removal of the tissue mass.

1 91. (New) A method of removing a tissue mass from a tissue using the tissue anchor of  
2 claim 83, comprising:

- 3 a. with the anchor members in their retracted positions, advancing the distal  
4 end of the elongate tube into the tissue mass;
- 5 b. thereafter, advancing the rod distally to its second position, thereby forcing  
6 the anchor members outwardly from the elongate tube and into the tissue  
7 mass;
- 8 c. thereafter, stabilizing the tissue mass with the tissue anchor while cutting the  
9 tissue; and
- 10 d. removing the tissue mass.

1 92. (New) A tissue anchor for stabilizing a tissue mass for surgical excision, comprising:

- 2 a. an elongate tube having a distal end, a central bore, a wall, and four  
3 apertures extending through the wall, the elongate tube being manually  
4 graspable and adapted to enable a length of the elongate tube to be inserted  
5 into the tissue mass;
- 6 b. a rod having a length which is slidably received in the central bore of the  
7 elongate tube, the rod being moveable distally with respect to the elongate  
8 tube from a first position; and
- 9 c. four anchor members, with one anchor member being associated with each  
10 aperture of the elongate tube, each of the anchor members being connected  
11 to the rod for movement therewith such that a majority of the length of each  
12 anchor member is received within the central bore of the elongate tube when  
13 the rod is in its first position and each anchor member moves outwardly from  
14 its associated aperture to assume a curved configuration to facilitate  
15 stabilization of the tissue mass when the rod is moved distally.

1 93. (New) A method of removing a tissue mass from a tissue, comprising:

- 2 a. providing a tissue anchor comprising an elongate tube having a distal end  
3 and a plurality of apertures; a manually controllable actuator; and a plurality  
4 of anchor members operatively connected to the actuator;
- 5 b. advancing the distal end of the elongate tube into the tissue mass to a  
6 desired location;

- c. thereafter, manually moving the actuator to deploy the anchor members outwardly from the elongate tube through the apertures, thereby forcing the anchor members into the tissue mass;
- d. thereafter, stabilizing the tissue mass with the tissue anchor while cutting the tissue; and
- e. removing the tissue mass.

94. (New) A method according to claim 92, wherein stabilizing the tissue mass includes drawing the tissue anchor proximally, thereby tensioning the tissue mass.

95. (New) A method according to claim 92, further comprising leaning the elongate tube and the elongate rod after the anchor members are deployed in the tissue mass to facilitate surgical removal of the tissue mass.

96. (New) A method of stabilizing a tissue mass during a medical procedure using a tissue anchor which includes an elongate tube having a distal end and a plurality of apertures; a manually controllable actuator; and a plurality of anchor members operatively connected to the actuator, the method comprising:

- a. grasping the elongate tube of the tissue anchor and advancing the distal end of the elongate tube into the tissue mass to a desired location;
- b. thereafter, manually moving the actuator to deploy the anchor members outwardly from the elongate tube through the apertures, with one anchor member advancing through each aperture such that the anchor members curve outwardly from the apertures, thereby extending the anchor members into the tissue mass;
- c. thereafter, manually grasping the tissue anchor to stabilize the tissue mass.

97. (New) A method according to claim 95, further comprising drawing the tissue anchor proximally after deploying the anchor members, thereby tensioning the tissue mass.

#### REMARKS

In the parent application, the Examiner issued a restriction requirement on 14 September 1999, requiring restriction between three separate inventions. Claims 32-36

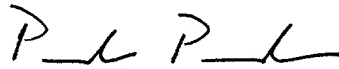


were identified as defining an independent and distinct invention relating to a "tissue anchor, classified in class 606, subclass 167." A preliminary amendment filed 28 February 2000 cancelled claims 32-36, among others, from the parent application. The present application cancels all of the original claims except claims 32-36 and adds new claims 65 - 97.

All of the pending claims, i.e., claims 32-36 and 65-97, are in condition for allowance. Applicant, therefore, requests prompt examination of the application and an allowance of all pending claims. If the Examiner wishes to discuss any aspect of this application, the Examiner is encouraged to contact Mr. Hotchkiss by telephone at the number listed below.

Respectfully submitted,

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